UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA [UNDER SEAL], PLAINTIFF, *v.* [UNDER SEAL], DEFENDANTS.	CIVIL ACTION NO. 06 C 6141 Judge Holderman **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

FIRST AMENDED COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA *EX REL.* ELAINE BENNETT PLAINTIFF, *v.* BOSTON SCIENTIFIC CORPORATION and GUIDANT CORPORATION DEFENDANTS.	CIVIL ACTION NO. 06-CV-6141 **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiff and qui tam relator Elaine Bennett, through her attorneys Sanford, Wittels & Heisler, LLP, for her Complaint against Boston Scientific Corporation and Guidant Corporation (hereinafter "Defendants") alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the Defendants and/or their agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., ("the FCA" or "the Act").

2. This qui tam case is brought against Defendants for conducting a fraudulent marketing and inducement campaign that foreseeably caused false or fraudulent claims for

procedures performed using Defendants' microwave ablation products to be presented to the Medicare program. As a direct result of Defendants' improper practices, the Federal Treasury has been damaged in a substantial amount yet to be determined.

3. Since the introduction of their microwave surgical ablation products, one of the largest obstacles Defendants have faced in selling their products is that their only cost-effective use is the off-label treatment of atrial fibrillation. Rather than lowering their prices and marketing their products for approved uses, Defendants initiated a coordinated nationwide sales campaign (including the use of illegal kickbacks and other improper means) to entice physicians and hospitals to use their products for off-label purposes.

4. For the majority of patients, cardiac ablation can be more safely performed, at a lower cost, as an outpatient catheter procedure in the catheterization lab. Inpatient admission is not medically necessary. However, through their aggressive off-label marketing campaign, Defendants have induced physicians and hospitals to use their inpatient cardiac ablation procedures.

5. Defendants have promoted their products to hospitals by highlighting the high spread between Medicare reimbursement for procedures performed with Defendants' products and the relatively low cost of those procedures. Defendants have encouraged cardio-thoracic surgeons to perform procedures using Defendants' products as a means of winning business for those surgeons.

6. Defendants have done more than just talk to physicians and hospitals about off-label uses for Defendants' products. In order to bolster this off-label marketing campaign, Defendants have given both hospitals and physicians kickbacks and other inducements to encourage them to buy and use Defendants' microwave surgical ablation products.

7. Defendants' sales representatives also provide free equipment, such as microwave

referral services to bring in more patients and business to the surgeons and to promote the surgeons as eminent physicians that provide this new cutting edge procedure. This in-kind marketing support by sales representatives includes marketing to other physicians (i.e., primary care physicians, family practitioners) who can directly refer those newly diagnosed atrial fibrillation patients to the cardiothoracic surgeons for surgery as a treatment option, eliminating the cardiologist, whose normal protocol for the treatment of atrial fibrillation is drug therapy and catheter ablation -- all done as outpatient procedures. By changing the normal course of referral patterns and replacing the referral to a cardiologist with direct referral to the cardiothoracic surgeon, the patient can then be referred for surgical ablation as a first line therapy instead of the outpatient therapy option that a cardiologist would provide for that same patient. These referral services provide an extremely valuable benefit for the surgeons in marketing their practice. This marketing support also promotes performance of additional microwave surgical ablation procedures and the purchase of more of Defendants' products.

11. The decline of cardiothoracic surgery has also caused many cardiothoracic surgeons to seek training for new treatments. Another in-kind benefit Defendants provide to physicians is direct, extensive training by sales representative and "ablation account managers" to teach the surgeons how to perform microwave surgical ablation for the off-label treatment of atrial fibrillation. In order to obtain this training, hospitals or physicians must agree to lock-in to an agreement to purchase and utilize Defendants' products.

12. As a result of Defendants' off-label marketing and illegal kickbacks campaign, a substantial number of patients have undergone more intensive, inpatient surgical ablation procedures, where less intensive, outpatient catheter ablation procedures (or other treatments) should have been

performed instead. The Medicare program has faced substantial increased costs for these inappropriate inpatient surgical procedures.

13. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

14. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

15. The Act allows any person having information about false or fraudulent claims to bring an action for herself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, qui tam plaintiff and relator Elaine Bennett seeks through this action to recover damages and civil penalties arising from the Defendants' knowing fraud on the U.S. Government.

II. PARTIES

16. Elaine Bennett is a resident of Saint Louis County, Missouri. Ms. Bennett was employed by Boston Scientific from June 12, 2006 to September 28, 2006 as a Sales Representative in the Midwest region and worked in both Central Illinois and throughout the state of Missouri.

17. Defendant Boston Scientific Corporation is headquartered in Natick, Massachusetts. Boston Scientific develops, manufactures and markets medical devices. On April 21, 2006, Boston Scientific acquired Guidant Corporation, subsuming Guidant's Cardiac Rhythm Management and Cardiac Surgery divisions. Since that time, Boston Scientific has been violating the False Claims Act by causing the submission of fraudulent Medicare claims for the off-label use of its microwave surgical ablation system to treat atrial fibrillation throughout the United States.

18. Defendant Guidant Corporation is headquartered in Indianapolis, Indiana. Guidant designs, develops and markets cardiovascular medical products, including the Flex 4, 10, and FlexView Microwave Surgical Ablation System. On April 21, 2006, Guidant's Cardiac Rhythm Management and Cardiac Surgery units became a part of Boston Scientific, and Guidant's vascular and endovascular businesses became a part of Abbott Vascular. Prior to that time, Guidant violated the False Claims Act by causing the submission of fraudulent Medicare claims for the off-label use of its microwave surgical ablation system to treat atrial fibrillation throughout the United States.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

20. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have at least minimum contacts with the United States. Moreover, the Defendants can be found in and transact – or have transacted – business in the Northern District of Illinois.

21. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the Defendants can be found in and transact – or have transacted – business in the Northern District of Illinois.

IV. BACKGROUND

A. THE MEDICARE PROGRAM

22. Medicare is a federally funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

23. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests and other medical services not covered by Part A.

24. The Centers for Medicare and Medicaid Services (CMS) administers Medicare but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as fiscal intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and

some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying claims for reimbursements under Medicare Part B

1. Medicare Payments to Hospitals

25. Medicare pays hospitals different amounts for various services based, in part, on the setting (e.g., inpatient or outpatient) where the services were performed. Hospitals are generally reimbursed for inpatient services on a "per case" basis. In other words, each inpatient hospitalization is assigned a Diagnosis Related Group ("DRG") based on the nature and severity of the patient's diagnosis and the services performed. Medicare then pays the hospital a pre-determined reimbursement rate based on the DRG. The pre-determined DRG reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided.

26. DRGs are assigned to a case through a process called "grouping." A "grouper" is a type of software that reviews various data related to the hospitalization (especially the patient's diagnosis and the procedures performed) to determine the appropriate DRG for the case.

27. In most cases, the procedure performed by the hospital is one of the most significant, if not the determinative, data point affecting the DRG grouper's decision. These procedures are classified and reported using International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system, established by CMS and the National Center for Health Statistics. These codes are commonly referred to as "ICD-9 procedure codes."

28. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

2. Medicare Payments to Physicians

29. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately from the hospital's DRG or APC payment.

30. Like hospital reimbursement, Medicare bases physician reimbursement on the assumption that similar types of procedures consume a similar amount of resources, and thus deserve similar reimbursement. Accordingly, Medicare reimburses physicians based on standardized procedure codes – HCPCS and CPT codes, as described below.

31. Each procedure code is assigned a weight or value (called a Resource Based Relative Value Unit or "RBRVU"), as determined by the Resource-Based Relative Value Scale ("RBRVS"). The payment level for any given procedure is then determined by multiplying the RBRVU value for the code times a conversion factor (which takes into account regional and other variable cost factors).

32. The RBRVS system is based on the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid and other federal health care programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to standardized codes.

33. Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA").

34. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Radiology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

35. The instructions that accompany the CPT manual direct providers "not [to] select a CPT code that merely approximates the service provided." Rather, when none of the standard CPT codes provides an accurate description of the services provided or procedure performed, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e., the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided).

36. Codes listed after each subsection in the CPT Manual and ending in -99 are "unlisted" codes. When a provider submits a claim with a "99" code, it must also provide supplemental information describing the procedure performed so that the carrier may determine the appropriate reimbursement. Correct code assignment occurs after this extra documentation for the claim is reviewed by the carrier

37. Physicians typically submit claims for professional services on Form CMS-1500. The claim form sets forth the diagnostic code describing the patient's presenting condition and the procedure codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient ...."

3. Other Rules Governing Payments to Both Hospitals and Physicians

38. In addition to compliance with other national or local coverage criteria, Medicare requires, as a condition of coverage, that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services and, then, provide such services only where medically necessary. 42 U.S.C. § 1320c-(a)(1). Providers must provide evidence that the service is medically necessary and appropriate. 42 U.S.C. § 1320c-5(a)(3). Providers must ensure that services provided are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6)&(8).

39. Federal law also specifically prohibits providers from making "any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program." See 42 U.S.C. § 1320-a-7b(a)(1). Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to the Medicare to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

40. It is unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship. See 42 U.S.C. §1395nn(a)(1).

B. THE ANTI-KICKBACK STATUTE

41. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, are of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs

from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

42. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has, as one of its purposes, inducement of a physician to perform additional procedures using the company's products.

43. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

44. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider in federal health care programs. Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

45. Any party convicted under the Anti-Kickback statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years.

42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services ("HHS") finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant state agency(ies) to exclude that provider from the state health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

C. TREATMENT OF ATRIAL FIBRILLATION, WITH AND WITHOUT ABLATION

46. Atrial fibrillation is a very fast and irregular beating of the atria. Atrial fibrillation is the most prevalent type of arrhythmia leading to hospital admission. Over 2.2 million Americans suffer from atrial fibrillation, and approximately 160,000 new cases are diagnosed every year.

1. Treatment of Atrial Fibrillation Without Ablation

47. Treatment with antiarrhythmic drugs and anticoagulation is considered first-line therapy in patients with symptomatic atrial fibrillation.

48. The cardiac "maze" procedure is a form of open-heart surgery used to treat atrial fibrillation with strategic placement of incisions in both atria. Since its introduction, the maze procedure has undergone three iterations: Maze I, II, and III, which all involve cut and sew techniques used during open-heart procedures. Despite its high success rate, the maze operation has not been widely adopted except for patients undergoing cardiac surgery because of the need for cardiopulmonary bypass, the morbidity and complication rates, and because it is a difficult and very challenging procedure for the surgeon to perform.

2. Treatment of Atrial Fibrillation with Ablation

49. In recent years, physicians have begun to try to treat atrial fibrillation by ablating – i.e., removing or destroying – certain heart tissue with various forms of energy (e.g., radio frequency, microwave). In general, physicians have experimented with two types of ablation procedures: (1) catheter ablation and (2) surgical ablation.

a. Catheter Ablation

50. Catheter ablation is a minimally invasive procedure that involves the use of a catheter that is threaded through the leg and into the heart. The catheter is equipped with a device that delivers radiofrequency waves to the arrhythmia source.

51. Catheter ablation is an outpatient procedure, performed by an electrophysiologist ("EP") in a catheterization lab. EPs are specialized cardiologists. In a catheter ablation procedure, the patient is awake with less anesthesia (under conscious sedation), experiences fewer side effects, and will go home the same day of the procedure.

52. Catheter ablation has recently gained recognition as an effective procedure to treat atrial fibrillation. A large number of studies have reported high rates of successful treatment and a low incidence of complications with the catheter ablation techniques.

53. The American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, and the European Society of Cardiology Committee for Practice are the premier medical societies that establish "standards of care" and treatment protocols for patients with cardiology conditions. In 2006, the Guidelines for patients with atrial fibrillation were updated to include catheter-based ablation as a third-tier treatment option, following drug therapy and cardioversion. This is the first time catheter-based ablation was included as a standard of care, because, until this time, catheter-based ablation had been considered experimental. Catheter-based

ablation has been used in practice for a much longer period of time (around 5 years) than surgical ablation, which is why surgical ablation is still considered experimental, and was not added to the recommended practices, or considered a "standard of care".

b. Surgical Ablation

54. Surgical ablation is a surgical procedure performed in the operating room with the patient under general anesthesia. The procedure is a derivative of the maze procedure using microwave (or other) energy to create lesions, rather than a cut and sew technique.

55. Surgical ablation procedures are generally performed by cardio-thoracic surgeons. Unlike catheter ablation procedures, which are performed on an outpatient basis, surgical ablation procedures are generally performed on an inpatient basis, requiring the patient to stay in the hospital.

56. There is not yet an efficacy study assessing the safety and efficacy of using microwave surgical ablation or any other energy source to perform surgical ablation for the treatment of atrial fibrillation.

57. Surgical ablation may be performed as either an open-heart procedure (often in conjunction with another open-heart procedure) or as a "minimally invasive" procedure.

58. A wide variety of minimally invasive forms of surgical ablation, including thoracoscopic epicardial ablation, are currently being investigated as potential forms of treatment for atrial fibrillation. Because the efficacy and safety of thoracoscopic surgical ablation are still under investigation, the procedure is considered more experimental and is less accepted than either catheter ablation or the maze surgical procedure.

59. A stand-alone, minimally invasive surgical ablation procedure – unlike traditional heart surgery – does not require opening the thoracic cavity to expose the heart and lungs and does

not require putting the patient on a heart-lung bypass machine to stop the heart. Patients treated with the minimally invasive, closed-chest procedure generally recover faster than those treated with procedures that require open heart access.

c. Surgical Ablation with Defendants' Microwave Surgical Ablation System

60. Defendants' surgical ablation system consists of a microwave generator and a surgical ablation probe that delivers a continuous flow of microwave energy from the generator to the cardiac tissue. The system is designed to ablate tissue by the induction of cell death in the targeted areas.

61. Defendants' microwave surgical ablation system can be used either in conjunction with open-heart surgery or as a stand-alone, minimally invasive procedure.

62. There is not yet an efficacy study assessing the safety and efficacy of using Defendants' minimally invasive microwave surgical ablation products to treat atrial fibrillation.

63. During the stand-alone, minimally invasive microwave surgical ablation procedure, the surgeon usually will make small incisions called ports in the patient's side. Typically, there are up to six ports in total (1/2" to 3/4" in size). Using an endoscope—a tiny camera that can be inserted into the ports—the surgeon is able to view the heart without having to open the chest cavity. The surgeon will then insert special instruments through the ports to perform the procedure, including the endoscope, small scissors, and graspers. These tools will help the surgeon move the Guidant FLEX Probe—a narrow, flexible device—into position to burn the lesion sets onto the surface of the heart. Lesions are necessary to stop the occurrence of atrial fibrillation. Using the Probe, the surgeon will then deliver targeted amounts of microwave energy to the heart. On average, the entire procedure usually takes three hours to complete.

D. MEDICARE COVERAGE OF ABLATION PROCEDURES

64. Typically, catheter ablation and surgical ablation are recommended as treatment for atrial fibrillation only when the patient is either intolerant of or resistant to drug therapy.

65. There is no National Coverage Determination for reimbursement for microwave surgical ablation. Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation.

66. Defendants have directed substantial effort to obtain coverage for microwave surgical cardiac ablation procedures through the Medicare Carriers.

67. As alleged herein, Defendants developed a marketing scheme to exploit high reimbursement under DRG 108 for the stand-alone surgical ablation procedure using their product to persuade hospitals to purchase their products. Under DRG 108, hospitals obtain an average reimbursement of $30,289. Because the average total cost to the hospital for use of Defendants' stand-alone, minimally invasive products is only $10,650, hospitals make a substantial profit whenever such a procedure is performed. Defendants heavily promote this fact as part of their campaign to get hospitals to perform surgical ablation procedures using Defendants' products.

68. Defendants also coach hospitals to "upcode" the minimally invasive, closed-chest, procedure to a procedure code for open-heart DRG 108 to take advantage of the Medicare care system and obtain an over-reimbursement of approximately $20,000 per a procedure.

V. ALLEGATIONS

A. DEFENDANTS ILLEGALLY MARKET THEIR PRODUCTS TO HOSPITALS AND PHYSICIANS

69. Since 2001, Defendants have aggressively marketed their surgical ablation products to induce hospitals and physicians to purchase their products and use them specifically (and only) for off-label treatment of atrial fibrillation.

70. In large part due to that aggressive and improper off-label marketing campaign, Defendants' microwave surgical ablation product has been used to treat atrial fibrillation in more than 1,600 stand-alone, closed-chest, thoracoscopic ablation procedures and in approximately 15,000 concomitant procedures (i.e., open-heart ablation procedures done in conjunction with another open-heart procedure).

71. Since approximately 2003, Defendants devised a strategy to further expand such off-label use of their product by marketing their minimally invasive, stand-alone products by advising hospitals to take advantage of the Medicare system to obtain over-reimbursement for such procedures.

1. Defendants Aggressively (and Exclusively) Promote Their Product for Off-label Treatment of Atrial Fibrillation

72. Although Defendants' microwave surgical ablation system is not FDA-approved for the treatment of atrial fibrillation, Defendants specifically market it for that use. In fact, that is the only practical, cost-effective use for their product, and the only use for the product that Defendants promote.

73. Defendants' microwave surgical ablation system is categorized as a Class II device, which, pursuant to 42 C.F.R. 405.201, "require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness."

74. The indicated use of microwave surgical ablation that was approved by the FDA in Defendants' 510(k) premarket notification was for *general use* in "the surgical ablation of soft tissue, and striated, cardiac, and smooth muscle." The system is a device "indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures."

75. When a device is approved by the FDA for a general use, a specific indication for use can become a new intended use that requires submission of an additional 510(k) approval to establish

the safety and effectiveness of the device.

76. The FDA has determined that the use of Defendants' product to treat atrial fibrillation is a specific indication for a new intended use, which requires an additional pre-market approval, due to considerations of safety and effectiveness.

77. There is not yet an efficacy study assessing the safety and efficacy of using Defendants' product to treat atrial fibrillation. Defendants have not completed their on-going study, entitled RESOLVE-AF (Randomized Study of Surgical Ablation with Microwave Energy for the Treatment of Atrial Fibrillation).

78. Defendants have not received FDA clearance or 510(k) approval supporting the specific use of microwave surgical ablation to treat atrial fibrillation.

79. The FDA has denied Defendants specific approval for the use of microwave surgical ablation to treat atrial fibrillation.

80. Notwithstanding the absence of specific approval, the only real-world, actual use of Defendants' microwave surgical ablation system is to treat atrial fibrillation. For example, all 15 references to clinical studies provided in Defendants' "white papers," their statement of proposed policy, pertain to the treatment of atrial fibrillation. There is not a single clinical study using the device on any condition other than atrial fibrillation.

81. Thus, all current uses of the microwave surgical ablation system are off-label. Moreover, the underlying purpose of all of Defendants' training and marketing of their microwave ablation system is to promote the off-label treatment of atrial fibrillation.

82. All of Defendants' sales activities, including promotion of high reimbursements, upcoding, kickbacks such as free products, free advertising, and referrals, are for the off-label promotion of Defendants' products to treat atrial fibrillation, which is experimental and not approved

by the FDA.

83. Defendants' sales representatives also promote the off-label use of Defendants' product by directly training doctors to use Defendants' microwave surgical ablation system to treat atrial fibrillation. Relator received extensive instructions regarding her responsibility to train doctors to use Defendants' product off-label to treat atrial fibrillation, including a ten-day "New Hire Training" that focused on using the FLEX Microwave Ablation System to treat atrial fibrillation. During this training, Relator and other new hires were introduced to the Maze procedure and other common techniques to treat atrial fibrillation, and then shown how use of microwave surgical ablation was a superior technique.

84. New hires were not taught to treat any condition other than atrial fibrillation with Defendants' product.

85. Among the instructional materials that Ms. Bennett received during the new hire training was a document that outlines the "seven basic steps" for using the Flex 10 procedure to treat atrial fibrillation, including the methods of routing, positioning, and applying lesion sets used during the procedure. Prior to finishing the training, Ms. Bennett was required to demonstrate to corporate trainers at Boston Scientific that she could "teach" proper lesion sets and surgical technique using Defendants' product to treat atrial fibrillation.

86. Relator and Defendants' other sales representatives were required to accompany surgeons into the operating room to provide surgeons with detailed instructions regarding how they could administer Defendants' product off-label to treat Medicare patients with atrial fibrillation.

87. Defendants have other employees called "Ablation Account Managers" who focus entirely on training surgeons to perform microwave surgical ablation to treat atrial fibrillation. These Ablation Account Managers are required to accompany the surgeons into the operating room the first

three times they perform microwave surgical ablation to provide the surgeon with detailed surgical techniques on how to treat atrial fibrillation with microwave surgical ablation.

2. Defendants "Market the Spread" – Emphasizing the High Reimbursement to Cost Ratio for Off-label Use of Their Product – as Part of their Aggressive Off-Label Pitch to Hospitals

88. Defendants aggressively promote the off-label use of their product by hospitals by "marketing the spread" between the high DRG reimbursement for atrial fibrillation procedures using their products and the low cost of those procedures. (The details of Defendants "marketing the spread" scheme are somewhat different than the practice as executed in the pharmaceutical industry, because Defendants do not have the same level of control over the reimbursement for their products as pharmaceutical companies do. In this case, however, Defendants' conduct has the same practical effect – namely, encouraging Hospitals to purchase their product simply because of the high profit margin the hospital will realize. Moreover, Defendants' aggressive promotion of the high profit margin hospitals can expect to see when Defendants' products are used to treat atrial fibrillation demonstrate that Defendants are aggressively promoting the use of their product for that one specific off-label use. Defendants also offer hospitals kickbacks and volume discounts that effectively reduce hospital costs and increase the hospitals' profit margins when they use Defendants' inpatient procedures).

89. Defendants' promotional literature and sales presentations to hospitals emphasize favorable reimbursement from Medicare as the central marketing theme used to induce hospitals and surgeons to purchase and use their products off label.

90. Defendants' sales representatives are trained to proposition hospital executives by asking them: "Would you like to learn about a procedure with a large, untreated patient pool and favorable reimbursement?" The sales representatives have a formal power point presentation

targeting CEOs and CFOs of hospitals, which shows the Medicare Part A payouts to hospitals incorporating atrial fibrillation programs within their institutions. The sales representatives are instructed to "describe [the] attractive reimbursement potential" and to emphasize "[favorable] procedure reimbursements and hospital economics" as "key message[s]" in their hospital executive briefings. In particular, a target objective is to "communicate the financial value of a [minimally invasive surgery] program." The sales representatives are also instructed to "go after" hospitals who have a "CEO and administration [that] understand [the] clinical and economic landscape."

91. Defendants' promotional presentations to hospitals point out that hospitals need to seek strategic and competitive growth opportunities in cardiac surgery. The promotional materials then provide an "economic assessment," alternatively referred to as an "economic map," of hospital reimbursement from Medicare.

92. Defendants boast in their promotional materials that, across the country, there is an estimated seven billion dollars a year to be made by hospitals from Medicare part A reimbursements for the treatment of atrial fibrillation.

93. Defendants' brochure, entitled an "economic map for hospitals treating patients with microwave surgical ablation," discusses Medicare fiscal year 2006 payment rates. Defendants state therein, "CABG [which refers to an open-heart procedure] reimbursement increases approximately $4900 when performed concomitant with microwave surgical ablation." Defendants, thus, advise hospitals that they can receive an average of $4,900 more from Medicare in CABG cases when they use Defendants' microwave surgical ablation system for the treatment of atrial fibrillation.

94. Defendants' brochure also points out that designation of microwave surgical ablation, as a stand-alone procedure, under DRG 108 will result in a $30,289 Medicare reimbursement and that: "Reimbursement for surgical ablation is higher than catheter ablation (DRG 518 = $8,524)."

The Defendants therefore promote their microwave ablation system to hospitals by instructing them that they can obtain a 355% higher reimbursement from Medicare if they use Defendants' microwave surgical ablation system, as a stand-alone procedure, instead of performing catheter ablation.

95. Furthermore, as set forth in greater detail below, Defendants also advise hospitals regarding a strategy to obtain an over-reimbursement of approximately 300%, or $20,000, by billing Medicare using the procedure codes (and resultant DRG codes) for open-heart surgery when, in fact, they perform stand-alone, closed-chest procedures. Defendants state in their promotional materials that the complete hospital cost of using the closed-chest, stand-alone procedure is $10,650, but that, by using the ICD-9 procedure code for open-heart surgery (which maps to DRG 108), hospitals can obtain a reimbursement of approximately $30,000, resulting in "an estimated contribution to margin" (i.e., profit for the hospital) of nearly $20,000.

3. Defendants Provide Improper Remuneration (Kickbacks) to Physicians and Hospitals To Induce Them To Purchase, Perform and Use Their Products for Off-label Procedures

96. As set forth below, Defendants routinely provide illegal kickbacks to physicians to induce them to perform procedures using Defendants' products, and to hospitals to induce them to buy Defendants' products and to promote their use by physicians who practice at the hospital.

97. Because compliance with the anti-Kickback statutes is a condition of payment, claims for reimbursement for procedures performed by a physician who has received a kickback or at a hospital that has received a kickback from Defendants are not eligible for reimbursement by Medicare.

98. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

a. Defendants Provide Improper Kickbacks, in the Form of Free Marketing and Promotional Services, to Physicians To Induce them to Perform Procedures Using Defendants' Products

99. Defendants provide physicians with tangible and in-kind services to induce performance of procedure and sales of their product. Some of the valuable in-kind services provided include marketing, advertising and referral services.

100. Defendants' marketing campaign specifically targeted cardio-thoracic surgeons, who, in recent years, have been losing business because of the increasing popularity of outpatient catheter ablation procedures. Defendants promoted surgical ablation procedures as a marketing tool for cardio-thoracic surgeons – i.e., telling the surgeons that they could advertise their proficiency in this cutting edge, high profile new treatment for atrial fibrillation.

101. As part of this effort – and in recognition of the cardio-thoracic surgeons' need to promote themselves to counter the rise of catheter-based treatment options – Defendants provide both marketing assistance and referral services to cardio-thoracic surgeons when they agree to perform procedures using Defendants' product. These services are valuable, and thus constitute remuneration for purposes of the anti-kickback statute.

102. For example, Defendants provide sponsored dinners and letter-writing services targeting physicians, such as primary care physicians and family practitioners, to avoid having patients referred to cardiologists and electrophysiologists, whose "standard of care" would be drug therapy and catheter-based ablation – all outpatient procedures. This is an attempt to change the standard of care treatment protocols for this patient population and allow for patients to have access to surgery as a first line therapy. This strategy also allows surgeons to treat a primary patient pool for the condition of atrial fibrillation, rather than having cardiologists treat this patient population first, which would eliminate the vast majority of patients being referred for surgery as a treatment option.

Cardiologists have access to drug therapy, catheter-based ablation, cardioversion, and pacemakers – all performed as outpatient procedures in the catheter labs by cardiologists and electrophysiologists in an attempt to treat atrial fibrillation. By encouraging the primary care physicians and family practitioners to refer directly to the cardiothoracic surgeons, Defendants are encouraging the creation of a new referral pattern in which the cardiothoracic surgeons are gaining an entirely new area of practice and hospitals are benefiting financially. Defendants then promote the cardiothoracic surgeons who have agreed to use Defendants' products by asking the referring physicians: "Did you know you have an experienced [minimally invasive surgery] ablation surgeon in your community? Did you know surgical ablation and catheter ablation have similar success rates (in patients with atrial fibrillation)?"

103. Similarly, Defendants directly drum up potential candidates for surgical ablation, and refer those potential patients to cardio-thoracic surgeons who have agreed to use Defendants' product. Defendants sponsor "town hall" meetings and community symposiums to screen for patients who are good candidates for their microwave surgical ablation procedures. Defendants then refer these screened patients to cardio-thoracic surgeons who perform their surgical ablation procedures.

104. Defendants also help cardio-thoracic surgeons who have agreed to use their product to increase their patient pool by providing free advertising services. Defendants pay for the design, publication, and marketing of brochures – including camera-ready art work – that advertise the surgeon's name, promote the surgeon as an excellent physician, and explain that the surgeon treats atrial fibrillation by using Defendants' microwave surgical ablation system. For example, Defendants provide print ads in newspapers, news journals, and other media that picture the surgeon and are entitled: "One Remarkable Procedure. One Remarkable Doctor."

105. Defendants also provide grants to surgeons who promote the procedure performed with their product. These grants are used to fund the training of new surgeons to use Defendants' product to treat atrial fibrillation. Defendants' marketing presentations list 12 surgeons that are provided with grants, brochures, and other incentives to promote the off-label use of Defendants' product: Dr. Balkhy, Dr. Beckman, Dr. Jansens, Dr. Kshettry, Dr. Srivastava, Dr. Pruitt, Dr. Masoor, Dr. Maessen, Dr. Williams, Dr. Molloy, Dr. Poa, and Dr. Saltman.

b. Defendants Provide Free Equipment and Special Discounts to Hospitals To Induce them to Purchase Defendants' Products, and to Discourage the Use of Competitor's Products

106. Defendants routinely provide kickbacks to hospitals in the form of free products or the free use of equipment, disguised in the form of discounts or equipment loans. Often these improper inducements are given on the explicit condition that the hospital will predominantly (or exclusively) use Defendants' products.

107. Defendants routinely provide hospitals with free products, including: (a) generators used to power Defendants' disposable equipment, worth approximately $28,000; and (b) disposable equipment used to perform surgical ablations, such as scopes, trays, and bovie cords. These gifts are given in exchange for the hospital's agreement not only to buy a targeted volume of Defendants' products, but also to give Defendants' products preferred status.

108. By receiving free products, hospitals reduce costs and increase reimbursement on each procedure performed. Because the DRG-based reimbursement to the hospital is fixed, the hospital pockets 100% of these "discounts."

109. Although these free gifts are often described in the contracts and invoices as simply "discounted" items, they do not comply with the Medicare anti-kickback safe harbor for legitimate discounts.

110. Similarly, although the gifts of microwave generators are often termed "loans" of the equipment, the arrangements do not comply with the Medicare anti-kickback safe harbor for legitimate equipment leases. In fact, the equipment is only "loaned" in exchange for a commitment to purchase a certain volume of Defendants' products, and the "loaned" equipment is never paid for.

111. Furthermore, these "discount" arrangements with hospitals routinely require the hospitals to ensure that Defendants products are used in a certain percentage (often 80% or more) of all surgical ablation procedures performed at the hospital. In such cases, any offered discounts are explicitly conditioned on the hospital's commitment to "lock in" a certain market share for Defendants' products.

112. Often, as part of these "lock in" arrangements, Defendants require the hospitals to turn over to Defendants all competitors' products and equipment from the hospital vicinity to ensure that the hospitals will use only Defendants' products. In some cases, Defendants' sales representatives disable the generators used to power the competitor's products (e.g., by taking the power cords and adaptors) to ensure that the hospital does not allow surgeons to use those competitor's products during surgical ablation.

113. These "discount" agreements also routinely offer the hospitals discounts on other products sold by Defendants – such as endoscopic vessel harvesting ("EVH") kits – in exchange for the hospital's commitment to buy a certain number of Defendants' ablation products (and to use those products in a fixed share of the hospital's surgical ablation procedures).

114. Defendants also offer bundling incentives to hospitals such that if a hospital buys three scopes, it will get one scope for free.

115. Defendants use these purported "discounts" (actually gifts of free goods – which result in higher profits for the hospitals) as leverage to induce the hospitals to buy more of

Defendants' products, regardless of whether another surgical ablation product (or a procedure other than surgical ablation) would have been more appropriate. Thus, these market-share commitments interfere with the discretion of the physicians to use the treatment that is in the best interest of each particular patient.

4. Defendants Coach Hospitals To Upcode and Overcharge Medicare for Closed-Chest, Stand-alone Procedures

116. Starting in approximately 2003, Defendants' sales and marketing departments trained their sales representatives to market their closed-chest, stand-alone, minimally invasive procedure by advising hospitals that they could obtain an over-reimbursement by billing Medicare with a DRG and procedure code for open-heart surgery.

117. Specifically, Defendants' managers including national sales representatives trained Relator and numerous other typical sales representatives to sell hospitals on the profit to be derived by billing Medicare for closed-chest, stand-alone procedures using DRG 108 with procedure code 37.33, which is a code for open-heart surgery.

118. Defendants' promotional brochure entitled "Guidant Microwave Surgical Ablation: Hospital Reimbursement," instructs hospitals to designate treatment of atrial fibrillation with their product under ICD-9 procedure code 37.33 (excision or destruction of other lesion or tissue of heart, open approach). ICD-9 procedure code 37.33 designates the use of "open chest" approaches, including the Maze procedure. Defendants' surgical ablation system, used as a stand-alone procedure, does not involve an open approach, and is in fact a minimally invasive closed-chest approach.

119. Because Defendants' stand-alone procedure is closed-chest, the hospital expenses associated with the procedure are significantly less than the hospital expenses for open-heart surgery.

120. The DRG code associated with procedure code 37.33, the code for open-heart surgery,

is DRG 108, which reimburses hospitals $30,289. The average length of hospital stay for patients who require procedures that qualify under DRG 108 is seven to twelve days. Correspondingly, the average hospital cost for patients who require procedures that qualify under DRG 108 is $31,074. In contrast, Defendants' closed-chest stand-alone procedure requires hospitalization for an average of only two to three days. Moreover, the average cost of Defendants' closed-chest, stand-alone procedure is only $10,650, approximately one-third of the average cost of procedures billed under DRG 108.

121. By promoting and encouraging the use of procedure code 37.33, which is designated for open-heart surgery, Defendants coached hospitals to obtain an over-reimbursement of nearly $20,000, or 300% higher than the hospital cost of the procedure, each time Defendants' microwave surgical ablation system is used as a stand-alone procedure.

122. Because there is no specific procedure code that provides reimbursement for the minimally invasive, closed-chest surgical ablation procedure, which is still considered an experimental and investigational procedure, a more appropriate code for the procedure would be procedure code 37.99 (other operations on heart and pericardium). Procedure code 37.99 is assigned to DRG 111 (Major Cardiovascular Procedures without Complications and Comorbidities) and DRG 110 (Major Cardiovascular Procedures With Complications and Comorbidities). DRG 111 would be the more appropriate of the two DRG codes for purposes of coding Defendants' stand-alone, minimally invasive procedure because the average length of hospital stay under DRG 111 is 3.43 days, whereas, the average length of hospital stay under DRG 110 is 8.4 days. The average Medicare reimbursement under DRG 111 is $12, 954, which corresponds more closely with the hospital costs of Defendants' minimally invasive, closed-chest procedure.

123. Defendants' promotional materials provide a case study of the exceedingly over-

priced reimbursement that a hospital stands to receive from Medicare by designating the codes, DRG 108 and procedure code 37.33, for the use of microwave surgical ablation as a stand-alone procedure. A slide in Defendants' marketing presentation entitled "[Redacted] Hospital Actual 2007 Medicare Reimbursement," which refers to Medicare reimbursement from October 2006 to September 2007, delineates that the hospitals will receive an actual Medicare reimbursement of $28,378, whereas, the cumulative cost of the entire procedure amounts to only $10,650. This $10,650 cost includes the average medical and procedural cost of ablation, Endo-Gia Stapler, purchase of the Flex 10 probe, three-hours use of the operating room, one-day placement in the Intensive Care Unit, two additional days hospital stay, and med-par costs. Thus, the remaining margin of profit from Medicare Reimbursements is $17,728 per a stand-alone procedure. If the hospital performs just one stand-alone procedure per month, the presentation further explains, the resulting profit from Medicare reimbursement is $212,736 per year.

124. Relator and Defendants' other sales representatives and Ablation Account Managers were instructed that they should promote Defendants' microwave surgical ablation system to treat atrial fibrillation by advising hospitals and doctors that if they used procedure code 37.33 and DRG 108 for the use of Defendants' product as a stand-alone procedure, they could obtain higher reimbursements from Medicare.

B. DEFENDANTS' RETALIATION AGAINST RELATOR

125. Relator has worked in the medical device industry for over 16 years. She has been recognized as a distinguished sales representative and has received President's Club awards in her previous employment in recognition of her position as a top ten percent sales producer.

126. Relator began her employment as a territory manager in the Cardiac Surgery (CS) Division of Guidant, a Boston Scientific Company, in June 2006.

127. Relator challenged the legality of Defendants' aforementioned marketing techniques, both during her initial training program and during a national sales meeting.

128. Relator was reprimanded, harassed and discharged by Defendants as a direct cause of her acts challenging Defendants' marketing approach as unlawful.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)-(2), (7)

129. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-128.

130. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 et seq.

131. As described above, Defendants have, through their off-label marketing campaign and the use of illegal kickbacks, caused physicians and hospitals to perform an increased number of costly inpatient surgical ablation procedures, in cases where less costly and less invasive treatments would otherwise have been done.

132. Through the acts described above, Defendants knowingly presented and caused to be presented to the United States fraudulent claims, records, and statements in order to obtain reimbursement for surgical ablation services performed with Defendants' microwave surgical ablation products.

133. Through the acts described above, Defendants knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for surgical ablation services performed with Defendants' microwave surgical ablation products.

134. The United States, unaware of the falsity or fraudulence of the statements, records or claims made or submitted by Defendants, their agents, and employees, approved, paid and continues to approve and pay claims that otherwise would not have been approved or paid, and has not recovered funds that would otherwise have been recovered.

135. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government, in order to obtain government reimbursement for health care services provided under Medicare.

136. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

COUNT II
False Claims Act
Retaliatory Discharge
31 U.S.C. §3730(h)

137. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-128.

138. Pursuant to 31 U.S.C. § 3730(h), the False Claims Act prohibits an employer from discharging, demoting, suspending, threatening, harassing, or in any other manner discriminating against an employee in the terms and conditions of employment because of lawful acts done by the employee in furtherance of an action under the Act.

139. Ms. Bennett's act of confronting Defendants and challenging the marketing techniques engaged in by Defendants was lawful conduct "in furtherance of" a False Claims Act action.

140. Relator's protected conduct put Defendants on notice of the distinct possibility of a qui tam action.

141. Defendants discriminated against Ms. Bennett in the terms and conditions of her employment by harassing her, threatening her, and discharging her because she confronted

Defendants regarding their aforementioned marketing approach.

COUNT III
Retaliatory Discharge in
Violation of Illinois Public Policy

142. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-128.

143. It is the public policy of the State of Illinois to prevent fraud against the government, fraudulent billing, and the off-label promotion of medical devices.

144. Relator had probable cause to believe that Defendants were violating public policy by improperly influencing and inducing hospitals and surgeons to use Defendants' ablation system.

145. Relator engaged in protected activity by challenging Defendants' fraudulent marketing techniques. As a result, she was subjected to retaliation and loss of position and wages when she was ultimately discharged effective September 28, 2006.

146. Defendants terminated Relator because she confronted Defendants and raised concerns that Defendants' ongoing marketing practices were illegal and fraudulent.

Prayer

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows:

1. that Defendants cease and desist from violating 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses;

5. that the United States and Plaintiff recover such other and further relief as the Court deems just and proper;

6. that Plaintiff be awarded the maximum amount she is entitled to, pursuant to 31 U.S.C. §3730(h) of the False Claims Act to make her whole, including two times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the retaliatory discharge, including litigation costs and reasonable attorneys' fees; and,

7. that Plaintiff be awarded relief pursuant to Illinois Public Policy to make her whole for the damages and financial losses suffered, including punitive and compensatory damages.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Dated: March 27, 2007

Respectfully submitted:

Lori E. Iwan/R.L.W.

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